UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,456	05/21/2007	Shlomo Magdassi	27576U	2276

20529 7590 04/27/2010

THE NATH LAW GROUP
112 South West Street
Alexandria, VA 22314

EXAMINER	
ALAWADI, SARAH	
ART UNIT	PAPER NUMBER
1619	

MAIL DATE	DELIVERY MODE
04/27/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/587,456	MAGDASSI ET AL.	
	Examiner	Art Unit	
	SARAH AL-AWADI	1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 January 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *41-44 and 46-65* is/are pending in the application.

4a) Of the above claim(s) *54-64* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *41-44,46-53 and 65* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of Applicants arguments/remarks filed 01/20/2010 is acknowledged. The Examiner acknowledges the following:

Claims 41-44 and 46-65 are pending.

Claims 41-44 and 46-53 and 65 are under Examination.

Claims 41, 42-44, and 46-53 are amended.

Claim 65 is newly added.

WITHDRAWN REJECTIONS

Rejections Under 35 U.S.C. 112 Second Paragraph

Claim 42 is rejected under 35. U.S.C. 112 second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter. The Examiner is interpreting the "single species" to include that of polymers that are made up of the same reoccurring monomers for example. In light of Applicants remarks said rejection is hereby **withdrawn.**

Claims 43-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants amendment to the claim renders said rejection moot. Therefore the rejection is hereby **withdrawn.**

Claim 47 is rejected under 35 U.S.C. 112 second paragraph for lack of antecedent basis. In light of Applicants amendment to the claim, said rejection is hereby **withdrawn.**

Claim 44 is rejected under 35 U.S.C. 112 second paragraph because the claim recited a broad range together with a narrow range. In light of Applicants amendments, said rejection is hereby **withdrawn.**

Double Patenting

Claims 41-43, and 50 are provisionally rejected on the ground of statutory type double patenting as being unpatentable over claims 6-12 copending Application No. 10/590621 further in view of Staniforth et al. United States Patent Application 2004/0265374 and Jonghwi Lee, Journal of Pharmaceutical Sciences, vol. 92, NO. 10, October 2003. In light of Applicants arguments/remarks and upon further reconsideration, said rejection is **withdrawn.**

Rejections under 103(a)

Claims 41-43 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cooper et al. WO 2004/011537 further in view of Jonghwi Lee, Journal of Pharmaceutical Sciences, vol. 92, No. 10, October 2003. In light of Applicants amendment, most notably to claim 41, said rejection is hereby **withdrawn.**

Claims 41-44 and 46-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soon-Shiong et al. United States patent Application 2002/0090399 further in view of Desai et al. United States Patent Application 2007/0092563. In light of Applicants amendment, most notably to claim 41, said rejection is hereby **withdrawn.**

MAINTAINED REJECTIONS

Claim Rejections - 35 USC § 103

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 51-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soon-Shiong et al. United States Patent Application 2002/0090399, Jonghwi Lee, Journal of Pharmaceutical Sciences, vol. 92, No. 10, October 2003, as evidenced by Desai et al. WO/2000/071079.

Claim 51 recites a drug delivery system comprising an active ingredient dispersed within a crosslinked polymeric bead wherein the crosslinking is by a cation such as copper, and wherein

the drug delivery system further comprises a chelator of calcium as a disintegrate. Claim 52 recites that the active ingredient is a poorly soluble drug. Soon-Shiong et al. teaches an embodiment with microcapsules of active agents wherein the outer layer can be polyionically crosslinked. Absent evidence to the contrary, the Examiner interprets beads to include that of polymeric hydrophilic micro or nanocapsules, furthermore Soon-Shiong teaches microcapsule are an example of beads. (see method of testing microcapsules paragraph 0147). Examples of polymers that can be polyionically crosslinked are hydrophilic polymers such as polyvinylpyridine. (paragraph 0075) Soon-Shiong further teaches that EDTA can be added to the microcapsule to disrupt the ionic crosslinking, thus acts like a disintegrate. (paragraph 0116) Soon-Shiong teaches that various drugs can be used with the polymer beads, one of which is an antiparkinson agent such as ethosuximide. (paragraph 0049) Ethosuximide (as evidenced by paragraph 0106 of Desai et al.) is known as a water insoluble (poorly soluble) drug. Regarding the disintigrate, Soon-Shiong et al. teaches that EDTA chelates cations such as calcium, zinc, barium, strontium ect. to disrupt ionic crosslinking of the microcapsule. (paragraph 0069 and 0116)

Soon-Shiong does not expressly teach that the poorly soluble drug is in the form of nanoparticles.

Jonghwi et al. teaches that reducing the particle size of an active agent improves the bioavailability of relatively insoluble drugs.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to minimize the microparticles of Soon-Shiong et al. to form nanoparticle systems because Jonghwi Lee et al. teaches an advantage such as increased bioavailibity. One

would have been motivated to reduce the particle size from microns to nanometers because Jonghwi Lee.teaches that doing so increases the surface area which greatly increases the dissolution rate.

Claims 41-44, 46, 50 and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Desai et al. WO/2000/071079 and Catron et al. US Patent 6,146,671.

Claim 41 recites a drug delivery system comprising nanoparticles or microparticles of a poorly soluble drug dispersed in a polymeric hydrophilic bead, the nanoparticles or micoparticle being in an amorphous non-crystalline state which enchances dissolution of the poorly soluble drug upon administration, and a disintegrate mixed within. Claim 42 recites that the drug according to claim 41 wherein the polymeric bead consists essentially of a single species of hydrophilic polymer.

Desai ‘079 teaches water insoluble active agents in nanoparticle or microparticle form (page 8, line 11) that are encased in a polymeric shell formulated from a biocompatible polymer. (page 1, lines 15-16) The polymer shell has a dispersing agent (disintegrate) which can dissolve the active agent. (page 1, lines 21-22) Desai further describes such polymers can be of polyvinyl alcohol (page 17, line 22) which is known to the skilled artisan to be a hydrophilic polymer, and that the delivery system can include that of beads. (page 15, line 19) Desai '079 teaches that the drug can be in amorphous form, which would lead to greater ease of dissolution and absorption resulting in better bioavailability. (page 10, lines 28-29 and page 11 lines 1-2)

Regarding claim 43 which recites that the polymeric bead is selected from a polysaccharide polymer, a synthetic polymer, and a protein, Desai '079 teaches that synthetic polymers can be used such as polyvinyl pyrrolidinone. (page 32, line 17)

Claim 44 recites that the drug delivery system according to claim 41 comprises a poorly soluble drug which can be selected to be an anti-parkinsonian agent. Desai '079 teaches various drugs can be used with the polymer beads, one of which is an antiparkinson agent such as ethosuximide. (column 27, line 15) Ethosuximide (as evidenced by paragraph 0106 of Desai et al.) is known as a water insoluble (poorly soluble) drug.

Regarding claim 46, Desai et al. teach the presence of crosslinking agents such as glutaraldehyde to crosslink the proteins.

Regarding claim 65, Desai et al. teach the use of poorly soluble drugs such as statins.

Desai '079 does not expressly teach that the beads are gelatin beads. (as recited in instant claim 50)

Catron et al. teaches the preferred use gelatin beads and suggests that gelatin beads act to protect the composition. (column 7, lines 7-8 , figure 2, and abstract) It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to select gelatin beads as the hydrophilic beads of Desai '079. One would have been motivated to do so with a reasonable expectation of success because the prior art teach gelatin as a preferred suitable polymer for use in beads. (column 7, lines 7-8 and figure 2 and abstract)

NEW REJECTIONS

In light of Applicants amendments which narrow the scope of claim 41, the following rejections are newly applied:

Claim Objections

Claim 65 is objected to because of the following informalities: The claim recites drugs such as statine or simvastatine. It is believed that Applicants meant to recite statin and simvastatin. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 41-43 and 46, rejected under 35 U.S.C. 103(a) as being unpatentable over Cooper et al. WO2004/011537, Jonghwi Lee, Journal of Pharmaceutical Sciences, vol. 92, No. 10, October 2003, and Chornet et al. United States Patent Application 2003/0157171.

Claim 41 recites a drug delivery system comprising nanoparticles or microparticles of a poorly soluble drug dispersed in a polymeric hydrophilic bead, the nanoparticles or microparticle being in an amorphous non-crystalline state which enhances the dissolution of the poorly soluble drug upon administration, and a disintegrate mixed within.

Cooper et al. teaches a drug delivery system comprising a polymer hydrophilic bead (poly vinyl alcohol) and a disintegrate (Sodium dodecyl sulphate) (Table 2, page 20) Cooper recites that hydrophobic active ingredients can be incorporated into the beads. (claim 19)

Claim 42 recites the drug according to claim 41 wherein the polymeric bead consists essentially of a single species of hydrophilic polymer. Cooper et al. teaches that the polymer bead can consist of poly vinyl alcohol which is a hydrophilic polymer. (page 8)

Claim 43 recites a drug delivery system of claim 42 wherein the polymer bead is selected from a polysaccharide polymer, a synthetic polymer, and a protein. Cooper et al. teaches an embodiment wherein the polymer bead can be polyvinylpyrrolidone. (table 7)

Claim 46 recites a drug deliver system according to claim 41, further comprising a crosslinker. Cooper et al. teaches that the porous beads can be crosslinked to enhance mechanical strength by cross linking agents such as 2,4-tolylene diisocynate. (see page 7)

Cooper et al. does not expressly teach that the poorly soluble drug is a nanoparticle or a microparticle dispersed in the polymer bead.

Jonghwi Lee teaches that reducing the particle size of an active pharmaceutical ingredient such as into microparticles or nanoparticles is an effective method to improve the bioavailability of relatively insoluble drugs. (page 1)

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to incorporate the hydrophobic drug of Cooper et al. into a microparticle or nanoparticle form. One would have been motivated to do so because Jonghwi Lee teaches mixing microparticles or nanoparticles with beads. (page 3) Furthermore, as evidenced by Jonghwi Lee, it is well known in the art that reducing the particle size of drugs results in improved bioavailability.

Neither Cooper et al. nor Jonghwi Lee teach the nanoparticles or microparticles in an amorphous non-crystalline State.

Chornet et al. teach methods of enhancing the dissolution rate of poorly soluble drugs. (pargraph 003)

It would have been prima facie obvious to the skilled artisan to form the microparticles or nanoparticles of the modified Cooper et al. in an amorphous non-crystalline state. One would have been motivated to formulate the drug particles in a non-crystalline amorphous state particularly in view of Chornet et al. which teach that enhancing the dissolution rate of poorly soluble drugs to increases their bioavailability is achieved by making drugs in amorphous form, see paragraph 003.

Claims 41-44, and 46-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soon-Shiong et al. United States Patent Application 2002/0090399, and Chornet et al. United States Patent Application 2003/0157171 as evidenced by Desai et al. United States Patent Application 2007/0092563.

Claim 41 recites a drug delivery system comprising nanoparticles or microparticles of a poorly soluble drug dispersed in a polymeric hydrophilic bead, the nanoparticles or microparticles being in an amorphous, non-crystalline state which enhances dissolution of the poorly soluble drug upon administration, and a disintegrate mixed within. Soon-Shiong et al. teaches an embodiment with microcapsules of active agents wherein the outer layer can be polyionically crosslinked. Absent evidence to the contrary, the Examiner interprets beads to include that of polymeric hydrophilic micro or nanocapsules, furthermore Soon-Shiong teaches microcapsule are an example of beads. (see method of testing microcapsules paragraph 0147). Examples of polymers that can be polyionically crosslinked are hydrophilic polymers such as polyvinylpyridine. (paragraph 0075) Soon-Shiong further teaches that EDTA can be added to the microcapsule to disrupt the ionic crosslinking, thus acts like a disintegrate. (paragraph 0116)

Soon-Shiong teaches that various drugs can be used with the polymer beads, one of which is an antiparkinson agent such as ethosuximide. (paragraph 0049) Ethosuximide (as evidenced by paragraph 0106 of Desai et al.) is known as a water insoluble (poorly soluble) drug.

Claim 42 recites a drug according to claim 41, wherein the polymeric bead consists essentially of a single species of hydrophilic polymer. Soon-Shiong teaches hydrophilic polymers can be used for the microcapsules such as polyvinylpyridine. (paragraph 0075)

Claim 43 recites that the drug delivery system of claim 41 can comprise a polymeric bead that is a synthetic polymer. As shown above, Soon-Shiong teaches polymer beads can include that of polyvinylpyridine which is an example of a synthetic polymer.

Claim 44 recites that the drug delivery system of claim 41 wherein the poorly soluble drug can include that of anti parkinson agents. As stated above, Soon-Shiong teaches that various drugs can be used with the polymer beads, one of which is an antiparkinson agent such as ethosuximide (paragraph 0049) Ethosuximide (as shown by paragraph 0106 of Desai et al.) is known as a water insoluble (poorly soluble) drug.

Claim 46 recites a drug delivery system according to claim 41, further comprising a crosslinker, and claim 47 recites wherein the crosslinker is a multivalent cation. Soon-Shiong et al. teaches that crosslinkers such as multivalent cations can be present which yield crosslinked microcapsules. (paragraph 0103)

Claim 48 recites that the drug delivery system of claim 41 contains a disintegrate that is capable of breaking the crosslinking by replacing or chelation of the crosslinking multivalent cation. Until some material difference(s) in the properties of the composition are demonstrated, said limitation is considered by the Examiner to be directed toward the drug delivery system

comprising a disintegrate which is instantly claimed. Furthermore, Soon-Shiong et al. teaches that disintegrates such as EDTA chelates the cations to disrupt ionic crosslinking the microcapsule. (paragraph 0116)

Claim 49 recites a drug delivery system according to claim 41, wherein the disintegrate is a calcium chelator. Soon-Shiong et al. teaches that disintegrates such as EDTA chelates the cations such as calcium, zinc, barium, strontium ect. to disrupt ionic crosslinking the microcapsule. (paragraph 0069 and 0116)

Soon-Shiong does not expressly teach that the poorly soluble drug is in the form of nanoparticles.

Jonghwi et al. teaches that reducing the particle size of an active agent improves the bioavailability of relatively insoluble drugs.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to minimize the microparticles of Soon-Shiong et al. to form nanoparticle systems because Jonghwi Lee et al. teaches an advantage such as increased bioavailibity. One would have been motivated to reduce the particle size from microns to nanometers because Jonghwi Lee.teaches that doing so increases the surface area which greatly increases the dissolution rate.

The modified Soon-Shiong does not expressly teach wherein the nanoparticles or microparticles are in an amorphous non-crystalline state.

Chornet et al. teach methods of enhancing the dissolution rate of poorly soluble drugs. (pargraph 003)

It would have been prima facie obvious to the skilled artisan to form the microparticles or nanoparticles of the modified Soon-Shiong in an amorphous non-crystalline state. One would have been motivated to formulate the drug particles in a non-crystalline amorphous state particularly in view of Chornet et al. which teach that enhancing the dissolution rate of poorly soluble drugs to increases their bioavailability is achieved by making drugs in amorphous form, see paragraph 003.

Claims 41 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mathiowitz et al. United States Patent, 6,528,035, Jonghwi Lee Journal of Pharmaceutical Sciences, vol. 92, No. 10, October 2003, Chornet et al. United States Patent Application 2003/0157171 as evidenced by Felt et al. Chitosan a Unique Polysaccharide article. (see 892 form)

Mathiowitz et al. teach microcapsules (beads) of polymers including gelatin which incorporate anesthetic or psychoactive drugs or cells. (see column 3, line 51 and column 2, lines 43-53 and abstract) One of ordinary skill in the art would have been particularly motivated to select gelatin beads as a preferred polymer of Mathiowitz in view of Felt et al. which teach that gelatin beads are advantageous as they entrap drugs more efficiently than polysaccharide beads. (see page 985)

Mathiowitz et al. does not expressly teach that the drug is a nanoparticle or a microparticle dispersed in the polymer bead (capsule).

Jonghwi Lee teaches that reducing the particle size of an active pharmaceutical ingredient such as into microparticles or nanoparticles is an effective method to improve the bioavailability of relatively insoluble drugs. (page 1)

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to incorporate the hydrophobic drug of Mathiowitz et al. into a microparticle or nanoparticle form. One would have been motivated to do so because Jonghwi Lee teaches mixing microparticles or nanoparticles with beads. (page 3) Furthermore, as evidenced by Jonghwi Lee, it is well known in the art that reducing the particle size of drugs results in improved bioavailability.

Neither Mathiowitz et al. nor Jonghwi Lee teach the nanoparticles or microparticles in an amorphous non-crystalline State.

Chornet et al. teach methods of enhancing the dissolution rate of poorly soluble drugs. (pargraph 003)

It would have been prima facie obvious to the skilled artisan to form the microparticles or nanoparticles of the modified Mathiowitz et al. in an amorphous non-crystalline state. One would have been motivated to formulate the drug particles in a non-crystalline amorphous state particularly in view of Chornet et al. which teach that enhancing the dissolution rate of poorly soluble drugs to increases their bioavailability is achieved by making drugs in amorphous form, see paragraph 003.

RESPONSE TO REMARKS

Applicants argue that Desai et al. is directed towards protein coatings of solid or liquid individual particles of the active agent. Applicants argue that neither Desai or Catron teach a drug delivery system comprising a plurality of nanoparticles or microparticles of a poorly soluble drug dispersed in a polymeric hydrophilic bead, the nanoparticles or microparticle being in an amorphous, non-crystalline state which enhances dissolution of the poorly soluble drug upon administration and a disintegrate mixed. Applicants describe that the presently claimed subject matter exhibits unexpectedly superior results over the cited art as described on page 7,10 and 12 of the specification. Applicants further argue that neither Desai or Catron teach or suggest evaporation of the solvent from already formed beads and that the presently claimed subject matter allows the use of a broad spectrum of stabilizers (surfactants).

In response, the Examiner respectfully submits that while Desai et al. teach one embodiment that comprises a protein coating, Desai et al. teach a further embodiment wherein water insoluble active agents in nanoparticle or microparticle form (page 8, line 11) are encased in a polymeric shell formulated from a biocompatible polymer. (page 1, lines 15-16) (see also 10th paragraph after detailed description) With regards to the unexpectedly superior results as decribed in page 7,10, and 12, the Examiner submits that the specification discloses that "it was surprisingly found that by performing the solvent evaporation process only after the beads are formed, the crystallization and increase of the size of the drug molecule could be prevented." With regards to page 12 the specification states "as the last stage (in the bead preparation) the volatile organic solvent is evaporated together with the aqueous phase to obtain the dry beads containing in their matrix dispersed nanoparticles of the poorly soluble drug." The Examiner respectfully submits that in response to applicant's argument that the references fail to show

certain features of applicant's invention, it is noted that the features upon which applicant relies (the specific steps in forming the bead i.e. evaporation of solvent) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The specific steps Applicants are referring to such as solvent evaporation techniques and the preparation of the beads appear to be directed towards methods of making the composition. The Examiner submits that the claims are directed towards a composition, therefore it is irrelevant what method steps are performed to formulate the end product.

CONCLUSION

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136 (a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarah Al-Awadi whose telephone number is (571) 270-7678. The examiner can normally be reached on 9:30 am - 6:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bonnie Eyler can be reached on (571) 272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SARAH AL-AWADI/
Examiner, Art Unit 1619

/Shanon A. Foley/
Primary Examiner, Art Unit 1619